

PATENT Docket No. 252312005706

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE TECH CENTER 1600/20

In the application of:

Stephen M. COUTTS et al.

Serial No.: 0

09/753,350

Filing Date:

December 29, 2000

For:

CONJUGATES OF T CELL EPITOPE

DEFICIENT IMMUNOGEN ANALOGS FOR HUMORAL ANERGY AND CHEMICALLY DEFINED NON-POLYMERIC VALENCY

PLATFORM MOLECULES

Examiner: To Be Assigned

Group Art Unit: 1653

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97AND § 1.98

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. The documents are on record in the related application Serial Number 08/769,041, filed December 18, 1996. Copies of the documents were submitted in an Information Disclosure Statement and/or Office Action directed to related application Serial Number 08/769,041, filed December 18, 1996 and/or application Serial Number 08/453,254 filed May 30, 1997 and/or application Serial Number 08/152,506 and/or application Serial Number 07/914,869 filed July 15, 1992 and/or application Serial Number 08/118,055 filed September 8, 1993 and, accordingly, copies pa-607214

are not included herewith. This protocol conforms with 37 C.F.R. §1.98(d) and M.P.E.P. 609(A)(2). Copies of the documents can be provided upon request by The Examiner. The Examiner is requested to make these documents of record in the application.

This Information Disclosure Statement is submitted:

C.F.R. § 1.97(e) are provided herein.

With the application; accordingly, no fee or separate requirements are required.
 Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.
 After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 A fee is required. A check in the amount of * is enclosed.
 A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly; no fee is believed to be due.
 After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee. Accordingly, a Petition requesting consideration of the Information Disclosure Statement, an authorization to charge our deposit account, and a Certification under 37

Applicants would appreciate the Examiner's initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 is to the best of my knowledge and is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by

third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

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Dated: August 8, 2001

Respectfully submitted,

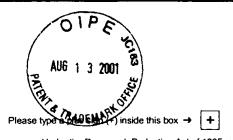
By:

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TRANSMITTAL
Filing Date December 29, 2000
First Named Inventor Stephen M. COUTTS

Group Art Unit 1653

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(to be used for all correspondence after initial filing)

Examiner Name

To Be Assigned

Total Number Of Pages In This Submission

8 Attorney Docket No. 252312005706

			Attorney Docket No.	25231200570	·			
ENCLOSURES (check all that apply)								
Fee Transmittal For	m		Assignment Papers (for an Application)		After Allowance Communication to Group			
Fee Attached			Drawing(s)		Appeal Communication to Board of Appeals and Interferences			
Amendment / Reply	1		Licensing-related Papers		Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)			
After Final			Petition		Proprietary Information			
Affidavits/de	eclarations		Petition to Convert to a Provisional Application		Status Letter			
Extension of Time F	Request		Power of Attorney, Revocation Change of Correspondence Add	lress 🔀	Other Enclosure(s) (please identify below):			
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Express Abandonm	ent Request		Request for Refund					
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Form PTO-1449

INFORMATION DISCLOSURE CITATION ON AN APPLICATION

(Use several sheets if necessary)

Docket Number 252312005706

Application Number 09/753,350

Applicant

Stephen M. COUTTS et al.

Filing Date December 29, 2000

Group Art Unit 1653

Mailing Date August 8, 2001

PADEMARKS

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U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
•	1.	12/21/1965	3,225,063	D'Alelio et al.			
	2.	03/04/1980	4,191,668	Katz			
	3.	09/02/1980	4,220,565	Katz			
	4.	04/26/1983	4,381,239	Chibata et al.			
	5.	06/14/1983	4,388,441	Katz			
	6.	03/17/1987	4,650,675	Borel et al.			
	7.	03/15/1988	4,731,373	Barner et al			
	8.	06/14/1988	4,751,181	Keene			- "
	9.	02/28/1989	4,808,705	Ferris			
	10.	06/12/1990	4,933,288	Greenfield			-
	11.	01/01/1991	4,981,979	Sivam			
	12.	06/30/1992	5,126,131	Dintzis et al.			
	13.	07/14/1992	5,130,116	Woo et al.			
	14.	11/10/1992	5,162,515	Conrad et al.			
	15.	12/07/1993	5,268,454	Barstad et al.			
	16.	01/04/1994	5,276,013	Conrad et al.			
	17.	12/06/1994	5,370,871	Dintzis et al.			
	18.	02/21/1995	5,391,785	Jones et al.			
<u></u>	19.	09/03/1996	5,552,391	Coutts et al.			
	20.	02/25/1997	5,606,047	Coutts et al.			
	21.	05/27/1997	5,633,395	Coutts et al.			
	22.	12/23/1997	5,700,919	Seliger et al.			
	23.	03/10/1998	5,726,329	Jones et al.			
	24.	07/28/1998	5,786,512	Jones et al.		-	
	25.	02/23/1999	5,874,409	Victoria et al.			
	26.	02/23/1999	5,874,552	Jones et al.			
	27.	02/08/2000	6,022,544	Dintzis et al.			

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

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INFORMATION TO GLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

Docket Number	252312005706
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Application Number 09/753,350

Applicant

Stephen M. COUTTS et al.

Filing Date December 29, 2000

Group Art Unit 1653

Mailing Date August 8, 2001

-	28.	05/09/2000	6,060,056	Coutts et al.	 	
	29.	03/27/2001	6,207,160	Victoria et al.		

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Transl YES	ation NO
	30.	09/30/1991	CA 2,079,109	Canada				
	31.	05/08/1991	DE 3,937,116	Germany			Abstract	
	32.	07/10/1985	EP 0 147 768	Europe			Abstract	
	33.	02/14/1990	EP 0 354 323	Europe				
	34.	11/281990	EP 0 399 330	Europe			Abstract	
	35.	07/24/1991	EP 0 438 259	Europe				
	36.	08/21/1991	EP 0 442 724	Europe				
	37.	03/15/1995	EP 0 642 798	Europe				
•	38.	01/11/1991	JP 3-5495	Japan			Abstract	
	39.	02/17/1986	JP 61-033195	Japan			Partial	
	40.	08/29/1985	WO 85/03704	PCT				
	41.	07/17/1986	WO 86/04093	PCT				
	42.	06/07/1987	WO 87/02777	PCT				
	43.	01/15/1987	WO 87/00056	PCT				
	44.	12/15/1988	WO 88/09810	PCT				
	45.	10/19/1989	WO 89/09628	PCT				
	46.	12/14/1989	WO 89/12060	PCT				
	47.	02/20/1992	WO 92/02531	PCT				
	48.	07/09/1992	WO 92/11029	PCT				
	49.	06/24/1993	WO 93/12145	PCT				
	50.	03/16/1995	WO 95/07073	PCT				
	51.	12/19/1996	WO 96/40197	PCT				
	52.	12/11/1997	WO 97/46251	PCT				

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INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

Docket Number 252312005706	Application Number 09/	753. 350			
Applicant Stephen M. COUTTS et al.			I DU		
Filing Date December 29, 2000	Group Art Unit 1653	ੋੜਹ ਨੂੰ-	UT.		
Mailing Date August 8, 2001		8			
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		OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.)
Examiner Initials	Ref. No.	Title
	53.	Agrawal et al., (1986) "Efficient Methods for Attaching Non-Radio-Active Labels to the 5' End of Synthetic Oligonucleotides," <i>Nucl. Acids Res.</i> 14:6227-6245.
	54.	Asseline, U. et al. (1990). "New Solid-Phase for Automated Synthesis of Oligonucleotides Containing an Amino-Alkylo Linker at Their 3'-End," <i>Tetrahedron Letts.</i> 31(1):81-84.
	55.	Borel et al. (1973). "Prevention of Murine Lupus Nephritis by Carris-Dependent Induction of Immunologic Tolerance to Denatured DNA," <i>Science</i> 182:76-78.
	56.	Borel et al. (1986). "A Possible New Therapy of Systemic Lupus Erythematosus (SLE)," Ann. N.Y. Acad. Sci. 475:296-306.
	57.	Borel et al. (1988). "Oligonucleotide Linked to Human Gammaglobulin Specifically Diminishes Anti-DNA Antibody Formation in Cultured Lymphoid Cells from Patients with Systemic Lupus Erythematosus," <i>J. Clin. Invest.</i> 82:1901-1907.
	58.	Borel et al. (1990). "A Novel Technique to Link Either Proteins or Peptides to Gammaglobulin to Construct Tolerogens," J. Immunol. Methods 126:159-168.
	59.	Conrad, M.J. et al. "Conjugates of Stable Polymer and Polynucleotide - Tolerogens for Human Systemic Lupus Erythematosus," Derwents Database record for European Patent No. EP 0 438 259, July 1991.
	60.	Dintzis, R.Z. et al. (July 1985). Inhibition of Anti-DNP Antibody Formation by High Doses of DNP-Polyacrylamide Molecules; Effects of Hapten Density and Hapten Valence," <i>J. Immunol</i> . 135(1):423-427.
	61.	Dreef, C.E. et al. (1988). "Synthesis of 1-O-(1, 2-DI-O-Palmitoyl-SN-Glycero-3-Phospho)-D-MYO-Inositol 4, 5-Biphosphate: An Analogue of Naturally Occurring (Ptd)Ins(4,5)P ₂ ," <i>Tetrahedron Letts</i> . 29(49):6513-6516.
	62.	Efimov, V.A. et al. (1993). "Synthesis of Polyethylene Glycol-Oligonucleotide Conjugates," <i>Bioorg. Khim.</i> , 19(8):800-804 (English abstract on page 804).
	63.	Eshhar et al. (1975). "Induction of Tolerance to Nucleic Acid Determinants by Administration of a Complex of Nucleoside D-Glutamic Acid and D-Lysine (D-GL)," J. Immunol. 144:872-876.
	64.	Frenkel et al. (1987). "Inhibition of RNA and DNA Polymerases by the Product of the Reaction of Selenite with Sulfhydryl Compounds," <i>Mol. Pharm.</i> 31(1):112-116.
	65.	Gupta, K.C. et al. (October 28, 1991). "A General Method for the Synthesis of 3'-Sulfhydryl and Phosphate Group Containing Oligonucleotides," <i>Chem. Abstracts</i> 115(17):976. (Abstract Only).
	66.	Hertler, A.A. (1988). "Human Immune Response to Immunotoxins," Cancer Treatment Research 37:475-480.

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Sheet 4 of 4 Application Number 09/753,350 Docket Number 252312005706 Form PTO-1449 DEMAR Applicant INFORMATION DISCLOSURE CITATION Stephen M. COUTTS et al. IN AN APPLICATION Group Art Unit 1653 (Use several sheets if necessary) Filing Date December 29, 2000 Mailing Date August 8, 2001 Jones, D.S. et al. (1994). "Conjugates of Double-Stranded Oligonucleotides with Poly(ethylene glycol) and Keyhole Limpet Hemocyanin: A Model for Treating Systemic Lupus Erythematosus," Bioconjugate Chem. 5:390-399. 68. Jones, D.S. et al. (1995). "Immunospecific Reduction of Antioligonucleotide Antibody-Forming Cells with a Tetrakis-oligonucleotide Conjugate (LJP 394), a Therapeutic Candidate for the Treatment of Lupus Nephritis," J. Med. Chem. 38:2138-2144. Kremsky et al. (1987). "Immobilization of DNA via Oligonucleotides Containing an Aldehyde or 69. Carboxylic Acid Group at the 5' Terminus," Nucl. Acids. Res. 15:2891-2909. Mitsuo, N. (1978). "Permeability of Liposomal Membranes Composed of Unnatural Types of 70. Synthetic Lecithin-Analogues," Chem. Pharm. Bull. 26(5):1493 Nossal, G.J.V. (14 July 1989). "Immunologic Tolerance: Collaboration Between Antigen and 71. Lymphokies," Science 245(4914):147-,153. Papalian, M. et al. (1980). "Reaction of Sytemic Lupus Erythematosus Antinative DNA Antibodies 72. with Native DNA Fragments from 20 to 1,200 Base Pairs," J. Clin. Invest. 65:469-477. Parker et al. (1974). "Modification of NZB/NZW F₁ Autoimmune Disease by Development of 73. Tolerance to DNA," J. Immunol. 113:292-297. 74. Sasaki et al. (1982). "Induction of Immunological Tolerance to Single-Stranded and Double-Stranded DNA," Scand. J. Immunol. 16:191-200. 75. Sehon, A.H. (1991). "Suppression of Antibody Responses by Conjugates of Antigens and Monomethypoly(Ethylene Glycol)," Advanced Drug Delivery Reviews 6:203-217. 76. Sehon. (1982). "Suppression of IgE Antibody Responses with Tolerogenic Conjugates of Allergens and Haptens," Prog. Allergy 32:161-202. Stollar et al. (1980). "Secondary Structure in Denatured DNA is Responsible for its Reaction with 77. Antinative DNA Antibodies of Systematic Lupus Erythematosus Sera," J. Clin. Invest. 66:210-219. Usman, N. et al. (1988). "Preparation of Glyceronucleoside Phosphoramidite Synthons and Their 78.

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Trav. Pays-Bas (no English Abstract).

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DATE CONSIDERED:

Use in the Solid Phase Synthesis of Acyclic Oligonucleotides," Tetrahedron Letts. 29(38):4831-

Wilkinson et al. (1987). "Tolerance Induction in Mice by Conjugates of Monoclonal

Immunoglobulins and Monomethoxypolyethylene Glycol," J. Immunol. 139:326-331.

Verkade, P.E. et al. (1940). "Synthesen von Glyceriden mit Hilfe von Tritylverbindungen IV," Recl.

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